



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SK276WO	FOR FURTHER ACTION See Form PCT/IPEA/416																	
International application No. PCT/JP2004/005515	International filing date (day/month/year) 16.04.2004	Priority date (day/month/year) 16.04.2003																
International Patent Classification (IPC) or national classification and IPC																		
Applicant SEKISUI CHEMICAL CO., LTD.																		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>9</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table border="0"><tr><td><input checked="" type="checkbox"/> Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/> Box No. II</td><td>Priority</td></tr><tr><td><input type="checkbox"/> Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/> Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/> Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input checked="" type="checkbox"/> Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/> Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input type="checkbox"/> Box No. VIII</td><td>Certain observations on the international application</td></tr></table>			<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report																	
Name and mailing address of the IPEA/JP	Authorized officer																	
Facsimile No.	Telephone No.																	

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Box No. I	Basis of the report
1.	<p>With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:</p> <p><input type="checkbox"/> international search (Rule 12.3 and 23.1(b))</p> <p><input type="checkbox"/> publication of the international application (Rule 12.4)</p> <p><input type="checkbox"/> international preliminary examination (Rule 55.2 and/or 55.3)</p>
2.	<p>With regard to the elements of the international application, this report is based on (<i>replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report</i>):</p> <p><input type="checkbox"/> the international application as originally filed/furnished</p> <p><input checked="" type="checkbox"/> the description:</p> <p>pages <u>1-33</u> _____ as originally filed/furnished</p> <p>pages* _____ received by this Authority on _____</p> <p>pages* _____ received by this Authority on _____</p> <p><input checked="" type="checkbox"/> the claims:</p> <p>nos. <u>4, 6, 8, 9, 16-22, 26</u> _____ as originally filed/furnished</p> <p>nos.* _____ as amended (together with any statement) under Article 19</p> <p>nos.* <u>2, 3, 5, 7, 10-15, 23-25</u> received by this Authority on <u>16.02.2005</u></p> <p>nos.* _____ received by this Authority on _____</p> <p><input checked="" type="checkbox"/> the drawings:</p> <p>sheets <u>fig. 1</u> _____ as originally filed/furnished</p> <p>sheets* _____ received by this Authority on _____</p> <p>sheets* _____ received by this Authority on _____</p> <p><input type="checkbox"/> a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.</p>
3.	<p><input checked="" type="checkbox"/> The amendments have resulted in the cancellation of:</p> <p><input type="checkbox"/> the description, pages _____</p> <p><input checked="" type="checkbox"/> the claims, nos. <u>1</u> _____</p> <p><input type="checkbox"/> the drawings, sheets/figs _____</p> <p><input type="checkbox"/> the sequence listing (<i>specify</i>): _____</p> <p><input type="checkbox"/> any table(s) related to sequence listing (<i>specify</i>): _____</p>
4.	<p><input type="checkbox"/> This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).</p> <p><input type="checkbox"/> the description, pages _____</p> <p><input type="checkbox"/> the claims, nos. _____</p> <p><input type="checkbox"/> the drawings, sheets/figs _____</p> <p><input type="checkbox"/> the sequence listing (<i>specify</i>): _____</p> <p><input type="checkbox"/> any table(s) related to sequence listing (<i>specify</i>): _____</p>

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
1. Statement	
Novelty (N)	Claims 2, 9, 15-22, 26 YES Claims 3-8, 10-14, 23-25 NO
Inventive step (IS)	Claims YES Claims 2-26 NO
Industrial applicability (IA)	Claims 2-26 YES Claims NO
2. Citations and explanations (Rule 70.7)	
	Document 1: JP 9-208788 A (Japan Synthetic Rubber Co., Ltd.), 12 August 1997 & US 5814687 A Document 2: JP 2003-14764 A (Matsushita Electric Industrial Co., Ltd.), 15 January 2003 & EP 1253427 A & US 2002/177234 A Document 1 discloses magnetic polymer particles that are configured by incorporating a magnetic material into a polymer, said magnetic polymer particles being characterized in that the number average particle diameter thereof is between 0.02 and 10.00 μm , and in that the polymer is configured from a copolymer that comprises: (A) 50 to 100 parts by weight of a constituent component that includes 20 to 90% by weight of the component (A1) and 80 to 10% by weight of the component (A2); (B) 0 to 50 parts by weight of an ethylenically unsaturated carboxylic acid; and (C) 100 parts by weight of a monomer mixture that includes 0 to 50 parts by weight of a vinyl monomer other than the monomers from the aforementioned components (A) and (B). Therein, document 1 indicates that the powdery supermagnetic material which is configured from an iron oxide has particle diameters of between 80 to 120 Å; that the

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magnetic polymer particles are produced from a monomer/magnetic material suspension by means of polymerization; that the component (A2) is a glycidyl (meth) acrylate; that styrenesulfonate is used as the vinyl monomer in component (C); that ethylene glycol dimethacrylate is added as a monomer component; that the content ratio of the supermagnetic material within the magnetic polymer particles is between 21 to 24%; and that it is possible to quantify antigens by bonding the antigens to magnetic polymer particles that have antibodies adsorbed thereto and thereafter magnetically separating the antigens therefrom.

In the invention that is disclosed in document 1 the ethylene glycol dimethacrylate, which is used as a component that constitutes the polymer, is a bifunctional crosslinkable monomer; therefore, the polymer that is disclosed therein can be considered to be a crosslinked polymer. In addition, styrenesulfonate is used as the vinyl monomer that constitutes the polymer; therefore, it is thought that sulfonic acid groups are present on the surface of the polymer in question.

Document 2 discloses the feature of using antibodies that have been labelled with a magnetic substance when taking measurements by means of a biodevice wherein the indicator substance holding section and the determination section have been configured from a porous material.

Claims 3 to 8, 10 to 14 and 23 to 25

The inventions set forth in claims 3 to 8, 10 to 14 and 23 to 25 lack novelty in the light of document 1 cited in the international search report.

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Claim 3 delimits the magnetic material-encapsulating particles by means of the production method therefor; however, the magnetic material-encapsulating particles that are obtained in the end are "magnetic material-encapsulating particles which encapsulate an organic polymer substance and iron oxide particles with an average particle diameter of 1 to 30 nm in a dispersed state within the particles." Therefore, there is no difference between the magnetic polymer particles from the invention that is disclosed in document 1 and the magnetic material-encapsulating particles from the invention that is set forth in claim 3 of the present application in terms of the configurations thereof.

In addition, the magnetic material that is disclosed in document 1 has been subjected to a lipophilization treatment. However, claim 3 does not make any disclosure in relation to a lipophilization treatment; therefore, the question of whether or not the magnetic material has been subjected to a lipophilization treatment has no bearing on the inventions that are set forth in the present application.

Furthermore, it is common practice to produce magnetic particles without modifying the surfaces of the magnetic material in order to impart lipophilic characteristics thereto (if necessary, refer to the documents JP 2000-40608 A and JP 4-3088 B2).

Claims 2, 9 and 15 to 17

The inventions set forth in claims 2, 9 and 15 to 17 do not involve an inventive step in the light of document 1 cited in the international search report.

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With regards to claim 2, it is common practice to attempt to configure so that the magnetic particles used in immunoassay methods have a uniform magnetic content (if necessary, refer to the document JP 2589618 B2); therefore, a person skilled in the art could configure so that the magnetic material has a uniform content ratio throughout the magnetic polymer particles that are disclosed in document 1, as appropriate. In addition, there is no critical technical significance to delimiting a range of 0.3 or less for the absolute deviation in the content ratio of the magnetic material throughout the magnetic particles in order to establish a reference for determining whether the magnetic material has a uniform content ratio; therefore, a person skilled in the art could delimit a range of 0.3 or less for the absolute deviation in the content ratio of the carbonic element that constitutes the organic polymer substance and the metal element that constitutes the magnetic material, as appropriate.

With regards to claim 9, polyethylene glycol methacrylate is a monomer that is commonly employed during the production of particles that contain a magnetic material; therefore, a person skilled in the art could configure so that polyethylene glycol methacrylate is added as a component of the magnetic polymer particles, as appropriate.

With regards to claims 15, 16 and 17, a person skilled in the art could configure so that the linkers for introducing an epoxy group that is capable of bonding with an antigen or an antibody are bonded to the magnetic polymer particles, and could further select a polyethylene glycol diglycidyl ether for use as the

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linker in question, as appropriate.

Claims 18 to 22

The inventions set forth in claims 18 to 22 do not involve an inventive step in the light of document 1 cited in the international search report.

With regards to claim 18, an organic peroxide compound is added to the monomer/magnetic material suspension as a polymerization initiator in the invention that is disclosed in document 1. However, the technical feature of obtaining a magnetic material by processing iron ions by means of an oxidizing agent is well known; therefore, it would have been easy for a person skilled in the art to conceive of substituting iron ions for the magnetic material that is added to the suspension in the invention that is disclosed in document 1 and then configuring so that the magnetic material is generated during the polymerization process that is initiated via the action of the polymerization initiator.

In addition, the magnetic material that is disclosed in document 1 has been subjected to a lipophilization treatment. However, claim 18 does not make any disclosure in relation to a lipophilization treatment; therefore, the question of whether or not the magnetic material has been subjected to a lipophilization treatment has no bearing on the inventions that are set forth in the present application.

Furthermore, it is common practice to produce magnetic particles without modifying the surfaces of the magnetic material in order to impart lipophilic characteristics thereto (if necessary, refer to the documents JP 2000-40608 A and JP 4-3088 B2).

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Claim 26

The invention set forth in claim 26 does not involve an inventive step in the light of document 1 and document 2 cited in the international search report.

It would be easy for a person skilled in the art to conceive of substituting the magnetic polymer particles that are disclosed in document 1 for the magnetic substance that is disclosed in document 2.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
JP 2004-163421 A	10.06.2004	21.10.2003	21.10.2002

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)